IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

UNITED STATES OF AMERICA, *ex rel.* JOHN STONE, and the States of Illinois, California, Florida, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, Virginia and Wisconsin, ex re. JOHN STONE,	)	
Plaintiffs,	)	Honorable James B. Zagel
v.	)	Civil Action No: 1:09-cv-04319
OMNICARE, INC.,	)	Magistrate Morton Denlow
Defendant.	)	

RELATOR'S RESPONSE IN OPPOSITION TO
OMNICARE, INC'S MOTION TO DISMISS RELATOR'S COMPLAINT

Relator John Stone ("Relator" or "Stone") by and through his undersigned counsel, respectfully submits this response in opposition to Omnicare, Inc.'s ("Omnicare" or "Defendant") Motion to Dismiss Relator's Complaint (Doc. #24). Relator prays this Court deny Defendant's Motion in its entirety. In the event Defendant's Motion is granted in any respect, Relator prays this Court grant Relator leave to amend his Complaint to correct any identified deficiency.

COUNT I

APPLICATION OF FERA AND PPACA TO THE RETENTION OF OVERPAYMENTS ALLEGED IN COUNT I DOES NOT CONSTITUE RETROACTIVE APPLICATION OF EITHER ACT

Relator's Complaint alleges that during 2007, Defendant performed an internal audit of its Medicare and Medicaid claims encompassing the period 2000-2005 for its facilities that provide

ancillary services ("Wave I").[1] The audit was conducted to ascertain whether such claims were in conformity with Medicare regulations, including the Program Integrity Manual CMS Publication #100-08, and state Medicaid regulations.[2] The Wave I audit results informed Omnicare that, for the years 2000 through 2005, systemic problems existed with respect to its pharmacy facilities' submissions of ancillary-related claims to the Medicare and State Medicaid programs, and that the "probe" sample did not identify the full extent of the problematic claims.[3] In a 2008 follow-up, Defendant performed a second internal audit ("Wave II") of fifteen pharmacy facilities. The Wave II audit consisted of examining 30 claims from each pharmacy facility for 2008 employing the criteria utilized in Wave I.[4] Again, Omnicare was made aware that its pharmacies had received payment for services which could not be substantiated.

Without further examination of the claims submitted during the period 2000 through 2005 and with knowledge of the Wave II audit results, Omnicare reimbursed each of the respective DMERC Regions A, B, C and D only for the Wave I findings,[5] failed to repay any of the State Medicaid programs,[6] and failed to inform the United States of, or repay the United States for, the federal portion of amounts expended under the various State Medicaid programs.[7]

On May 20, 2009, Congress enacted the Fraud Enforcement and Recovery Act ("FERA")[8] which amended the False Claims Act ("FCA"). The effective date of those amendments is set forth as follows:

> 4(f) EFFECTIVE DATE AND APPLICATION. The amendments made by this section shall take effect on the date of enactment of this Act [May

[1] Complaint (Doc. #1), ¶19
[2] *Id*., ¶20.
[3] *Id*., ¶30.
[4] *Id*., ¶31.
[5] *Id*., ¶33.
[6] *Id*., ¶34.
[7] *Id*., ¶35.
[8] Pub. L. No. 111-21 §4, 123 Stat 1617.

> 20, 2009] and shall apply to conduct on or after the date of enactment, except that—
> (1) subparagraph (B) of section 3729(a)(1) of title 31, United States Code, as added by subsection (a)(1), shall take effect as if enacted on June 7, 2008, and apply to all claims under the False Claims Act (31 U.S.C. 3729 *et seq*.) that are pending on or after that date; and
> (2) section 3731(b) of title 31, as amended by subsection (b); section 3733, of title 31, as amended by subsection (c); and section 3732 of title 31, as amended by subsection (e); shall apply to cases pending on the date of enactment.

Defendant contends that Relator has pled the wrong version of the FCA because "[t]he FERA revisions took 'effect as if enacted on June 7, 2008, and shall apply to all claims under the False Claims Act that are pending on or after that date.'"[9] According to Defendant, the FERA reference to "claims . . . pending on or after that date" refers to "claims for payment, not lawsuits."[10] By Defendant's reasoning, because Count I deals with claims made between 2000 and 2005, and again in 2008, such "claims" were pending prior to June 7, 2008. Defendant is mistaken.

On the date Relator filed his Complaint, July 17, 2009, the FERA amended FCA was the law of the land and that law applied to *conduct* on or after May 20, 2009. Post-FERA FCA liability attaches for so-called "reverse false claims" when any person "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government. . . ."[11] The term "obligation", as defined by the act, means "an

[9] Memorandum of Law in Support of Motion to Dismiss ("Memo in Support") (Doc. #25), pg. 7. To clarify, Defendant is wrong when it states that FERA categorically applies to claims that were pending on after June 7, 2008. In fact, the effective date of the FCA amendments is for *conduct* on or after May 20, 2009, *except for* those claims brought pursuant to former section 31 U.S.C. §3729(a)(2). §3729(a)(2), pre-FERA, provided for liability to any person who "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." Post-FERA, the provision is codified as 31 U.S.C. §3729(a)(1)(B) and reads "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."

[10] Memo in Support, pg. 7.

[11] 31 U.S.C. §3729(a)(1)(G) finds liability for any person who "knowingly makes, uses, or causes to made or used, a false record or statement material to an obligation to pay or transmit money or property to the

established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, *or from the retention of any overpayment*." (emphasis added).[12] According to the Oxford American Dictionary, "retention" is defined as "retaining" while the term "retain" is defined as "to keep in one's possession or use" or "to continue to have, not lose."[13] Because a statutory provision must be construed "in accordance with its ordinary or natural meaning"[14], "retention of an overpayment" must be deemed a continuing violation of the False Claims Act. On May 20, 2009, FERA's amendments applied to Omnicare's continuing conduct of possessing known overpayments and, when Relator filed his Complaint on July 17, 2009, he simply alleged the current state of the law and facts on that date. The conduct alleged in Count I constitutes a viable reverse false claim under the FERA-amended FCA.

As demonstrated by the following Count I allegations, there can be little question that Relator's Complaint alleges the predicate facts to establish reverse false claims liability on the date of filing:

> 33. Without further examination of the claims submitted during the period 2000 through 2005 – despite an enormous error rate and having conducted only a "probe" audit – and with knowledge of the Wave II audit results, Defendant reimbursed each of the respective DMERC

Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government."

[12] 31 U.S.C. §3729(b)(3).

[13] Oxford American Dictionary, 774-775 (1986).

[14] *FDIC v. Meyer*, 510 U.S. 471, 476 (1994).

> Regions A, B, C and D for the Wave I findings and falsely asserted that the Medicare program was made whole by that payment.[15]
>
> 34. While possessing knowledge of the deficiencies discovered during the Wave I and Wave II audits, Defendant failed to repay any of the State Medicaid programs for false and fraudulent claims submitted.
>
> 35. While possessing knowledge of the deficiencies discovered during the Wave I and Wave II audits, Defendant failed to inform the United States of, or repay the United States for, the federal portion of amounts expended under the various State Medicaid programs.

That the "retention of an overpayment" constitutes a continuing violation of the False Claims Act is entirely consistent with FERA's purpose. While FERA newly-amends the FCA, there can be little question that its purpose, to a substantial degree, is backward looking: to safeguard and recover federal funds distributed *prior to its enactment*. The application of FERA to protect such monies is precisely what Congress had in mind as the Senate Report to FERA makes abundantly clear:

> In response to the economic crisis, the Federal Government has obligated and expended more than $1 trillion in an effort to stabilize our banking system and rebuild our economy. These funds are often dispensed through contracts with non-governmental entities, going to general contractors and subcontractors working for the Government. Protecting these funds

[15] That these payments may have been made prior to May 20, 2009, has no bearing on the continuing conduct of retention after that date. According to ¶3 of Relator's affidavit attached hereto as Exhibit A, though, the payments may have actually occurred *after* the enactment of FERA. If so, this conduct would clearly constitute a separate and distinct act of knowing concealment or improper avoidance of an obligation to the Government.

> from fraud and abuse must be among our highest priorities as we move forward with these necessary actions.[16]

In simplest terms, if FERA does not apply to the post-FERA retention of known overpayments simply because *something* happened pre-FERA, it is difficult to see how FERA would ever apply in the recoupment of stimulus-related overpayments. Such a holding would be inconsistent with the purpose of FERA and strip the U.S. Government of a critical recoupment tool.

Further evidence of Congress' intent to recover known overpayments is found in the Patient Protection and Affordable Care Act ("PPACA").[17] Section 6402 of PPACA, which became effective on March 23, 2010, established a 60-day deadline for providers to repay and report overpayments of federal funds. The obligation under PPACA to return and report overpayments is specifically linked to the False Claims Act insofar as "[a]ny overpayment retained by a person after the deadline for reporting and returning the overpayment. . . is an obligation [as defined in the False Claims Act]."[18] Because the effective date of the statutory provision was March 23, 2010, providers who received and identified overpayments as of that date had until May 22, 2010, to comply with the obligations of the new deadline. While the FERA amendments specifically addressed liability for the retention of overpayments, PPACA's 60-day deadline established in all cases definitive "outer boundaries" regarding when liability would attach.

With respect to Omnicare's retention of overpayments as alleged in Relator's Count I, PPACA is effective for the following reason: on March 23, 2010, Omnicare was aware that it

[16] S.Rep.No. 110-10 at 10 (2009).
[17] Pub.L. 111-148, 124 Stat. 119.
[18] PPACA §6402(a).

was in possession of government monies to which it was not entitled. It had until May 22, 2010,[19] to report and return those overpayments. It failed to do so.

Omnicare cites the following language from *Graham County Water and Soil Dist. v. U.S. ex rel. Wilson* to argue PPACA's inapplicability: "The legislation makes no mention of retroactivity, which would be necessary for its application to pending cases given that it eliminates petitioners claimed defense to a *qui tam* suit." [20] *Graham* is easily distinguished from the instant case. While Count I of Relator's Complaint addresses the continuing retention of known overpayments, *Graham* was concerned with application of an amendment to the "public disclosure" bar of the FCA. That bar deprives courts of jurisdiction over qui tam suits when, in certain circumstances, relevant information has already entered the public domain. Had the Court retroactively applied PPACA, the defendant would have been deprived of a defense that existed prior to PPACA's enactment. In the instant case, application of PPACA to Omnicare's *continuing conduct* --- including post March 23, 2010 --- does not eliminate any of Defendant's defenses.

Relator is cognizant that courts apply a presumption against retroactive legislation unless Congress has clearly manifested its intent to the contrary. PPACA's application here, however, does not implicate retroactivity. Such application doesn't take away or impair vested rights under existing law, create any new obligations, impose any new duties, or attach any new disability in

[19] It is well to remember that, while this case was filed on July 17, 2009, it was not unsealed until June 11, 2010 – after PPACA's enactment. Omnicare was not aware of the instant case until the undersigned phoned Omnicare's general counsel, Mark Kobasuk, on July 8, 2010. Needless to say, neither the enactment of FERA nor PPACA caused a change in Defendant's on-going conduct. Relator maintains that, because the conduct was continuing, he could have appropriately amended his Complaint post-PPACA to incorporate PPACA pursuant to the Federal Rules. Should the Court find Relator's Complaint defective in its failure to cite PPACA, Relator requests leave to amend his Complaint to incorporate that statute.

[20] Memo in Support, pg. 7, *quoting Graham County Water and Soil Dist. v. U.S. ex rel. Wilson,*130 S.Ct. 1396, 1400, n.1 (2010).

respect to transactions already past. Relator's application of FERA and PPACA to Count I overpayments does what we normally expect a statute to do: become operative on the day it is enacted and regulate conduct from that day forward.

COUNT I: OVERPAYMENTS AND "PAPERWORK DEFICIENCIES"

In the face of its own audit which revealed systemic problems with ancillary services billing, its knowing repayment of only a portion of the overpayments it discovered, and the exhibits attached to the Complaint evidencing *claims level* information which it itself acknowledged necessitated a "refund", Defendant maintains that it has not been retaining government overpayments. Omnicare argues that Relator has failed to identify any statute that ties a pharmacy's possession of paperwork to payment of a claim.[21] Principally, Defendant claims that "[w]hile there are regulatory requirements relating to paperwork necessary to support Medicare and Medicaid claims, Relator has failed to allege these regulatory provisions, or explain how failure to locate paperwork during an audit is retroactively converted to a false claim."[22] Such "paperwork deficiencies", according to Defendant, cannot amount to a false claim actionable under the FCA.

To the contrary, Relator's Complaint with respect to Medicare alone contains numerous regulatory provisions specifically prohibiting the kind of conduct which Omnicare dismisses as "paperwork deficiencies." Such examples derive from the Medicare Integrity Manual CMS Publication #100-08 ("Manual") pertaining to Durable Medical Equipment, Prosthetic, and Orthotic suppliers' Medicare and Medicaid reimbursement of claims. Those provisions include 5.2.1 through 5.8[23] and pertain to requirements to keep on file a signed physician prescription; that a supplier must have an order from the treating physician before dispensing any DMEPOS

[21] Memo in Support, pg. 10.
[22] Id., at 11.
[23] Complaint, ¶21a-f.

item to a beneficiary; that detailed written orders are required for all transactions involving DMEPOS…and must clearly specify the start date of the order; that if the supply is a drug, the order must specify the name of the drug, concentration (if applicable), dosage, frequency of administration, and duration of infusion (if applicable). The supplier must have a detailed written order prior to submitting a Medicare claim; that a Certificate of Medical Necessity (CMN) or a DME Information Form (DIF) is a form required to help document the medical necessity and other coverage criteria for selected DMEPOS items. The list goes on.

Relator's Complaint at paragraph 23 lists numerous *actual* deficiencies found in the Wave I audit, among them "missing or inadequate proof of delivery documentation." Suppliers are required to maintain proof of delivery documentation for a period of 7 years.[24] This is done to verify that the beneficiary actually received the DMEPOS, verify the condition of the DMEPOS, and verify that the recipient was provided oral or written instruction for use of the equipment. With respect to "proof of delivery" documentation alone --- leaving aside all of the other myriad examples set forth --- the Center for Medicare and Medicaid Services is quite clear in its direction to suppliers:

> Proof of delivery is required in order to verify that the beneficiary received the DMEPOS. Proof of delivery is one of the supplier standards as noted in 42 CFR 424.57(12). Proof of delivery documentation must be made available to the DME MAC upon request. For any services, which do not have proof of delivery from the supplier, such claimed items and services *shall be denied and* ***overpayments***[25] *recovered* (emphasis added).[26]

[24] It should be noted that states vary with regard to the length of time that providers are required to maintain proof of delivery. For instance, unless additional retention is necessitated by a provider agreement, the Colorado Department of Health Care Policy and Financing ("HCPF") requires providers to maintain records for a minimum of 6 years. 10 CCR 2505 8.130.2.D.

[25] States have similar overpayment recovery mechanisms. For instance, Colorado HCPF requires that "[i]n the event that an audit … reveals that a provider is indebted to the State for any reason, the Department shall recover this amount either through a repayment agreement with the provider; or by offsetting the amount owed against current and future claims of the provider; or through litigation; or by any other appropriate action within its legal authority." 10 CCR 2505 8.040.

Examples such as this indisputably refute Omnicare's argument that Relator "has failed to allege that services were not provided or that the necessary documentation does not exist."[27] For one to suggest that the Complaint fails to allege that necessary documentation does not exist is to patently disregard the Complaint on its face. Defendant's twisted logic asserts, essentially, that although no documents can be found to substantiate claims made, no one can prove services weren't provided. The opposite is true under the law: the absence of documentation precludes Omnicare from arguing that services were, in fact, provided. The whole point of maintaining documentation is to verify that services were provided. In the end, Omnicare's self-identified failure to evidence the propriety of its claims for payment constitutes a present day overpayment.

Defendant further contends that, because FERA should not apply to this case, an overpayment alone is insufficient to state a claim under the FCA.[28] Defendant cites the *U.S. ex rel Yannacopoulos v. General Dynamics* decision for the proposition that "retention of an overpayment did not create an obligation under the former provisions of the FCA."[29] Defendant mischaracterizes Relator's allegations. Relator is not attempting to apply pre-FERA §3729(a)(7) to Defendant's retention of government overpayments; instead, as stated above, because Defendant's *conduct* occurred after the enactment of FERA, Defendant violated post-FERA §3729(a)(1)(G).

Furthermore, *Yannacopoulos* is clearly distinguishable from the case at bar. There, the Relator asserted that a contract for the sale of military aircraft carriers to Greece, funded through

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[26] Medicare Program Integrity Manual, Chapter 4, Benefit Integrity, §4.26, Supplier Proof of Delivery Documentation Requirements.
[27] Memo in Support, pg. 5.
[28] *Id.* pg 11.
[29] *Id.*

U.S. loans, resulted in a violation of the FCA.[30] Under that contract, the Defendant was paid fixed amounts quarterly and was contractually obligated to refund to the United States any overpayments through a contractual reconciliation provision.[31] Although the defendant complied with the terms of the contract by paying back to the United States all known overpayments, Relator alleged that the contract created an inherent "fixed sum immediately due and payable" and, thus, violated the reverse false claims component of the FCA.[32] The Court noted that because the relevant conduct occurred over a decade before FERA was enacted, FERA was not applicable.[33] Under the pre-FERA §3729(a)(7) case law-imposed requirement for a "fixed sum immediately payable," the Court held that the Defendant did not have a "present duty" to pay a "fixed sum" as evidenced by the defendant's compliance with the contractual provision allowing for reconciliation with the United States at a date subsequent to the United States' fixed quarterly payment.[34]

Unlike *Yannacopoulos*, where the relevant conduct occurred at least a decade prior to FERA's enactment, the present case involves Defendant's retention of government overpayments after the enactment of FERA. Further, the defendant in *Yannacopoulos* reconciled with the United States prior to the enactment of FERA. It remains unclear whether the Court would have held otherwise had the defendant retained government overpayments past FERA's enactment. Such an inquiry is irrelevant, however, as the contract at issue in *Yannacopoulos* specifically provided for the reconciliation of identified government overpayments.[35] There is no similar contractual requirement in the present case. Instead, Defendant identified government

[30] *U.S. ex rel Yannacopoulos v. General Dynamics*, 636 F.Supp.2d 739, 748 (N.D. Ill. 2009).
[31] *Id.* at 750.
[32] *Id. at 750-51.*
[33] *Id. at 751*.
[34] *Id*. at 750-52.
[35] *Id.*

overpayments, provided a partial payment with the intention of deceiving the United States of additional repayment obligations, and has continually retained overpayments through the date of this filing.

RELATOR HAS PLEADED COUNTS I AND II WITH PARTICULARITY

Defendant argues that Count I should be dismissed for failing to plead fraud with particularity as required by Federal Rule 9(b). Specifically, Defendant claims that Relator has failed to precisely allege what was false about the Defendant's claims for payment. Further, Defendant contends that while Relator alleges that Exhibits A-E represent documentation deficiencies in Omnicare pharmacies, these exhibits do not identify what was submitted to the government in support of each claim, what allegedly false statement or other falsity the unidentified submission contained, or the date on which a claim was actually submitted to the government for payment. With respect to Exhibits F and G, Defendant states that Exhibit F "lists the various controls tested and identifies whether pharmacies that were audited passed or failed. Yet nothing in the Complaint explains these tests, links the tests to the submission of a claim, suggests that the tests are required for reimbursement, or alleges how a control test failure retroactively creates a false claim."[36] Exhibit G "provides essentially the same information presented in Exhibit F, but with respect to a particular pharmacy."[37] Finally, Defendant asserts that Relator has failed to provide a basis upon which to extrapolate the data he provided beyond the probe-audit samples.

Defendant is shockingly unfamiliar with the contents of its own documents. Exhibit A, for example, consists of examples of *claims* level information for the states of Colorado, Illinois,

[36] Memo in Support, pg. 14.
[37] *Id*., pg. 15.

Louisiana, Nevada, and Washington.[38] Each of the charts are beneficiary specific (with names redacted), reflect specific dates of service, precisely what is wrong with the claim submitted (i.e. physician order missing, proof of delivery missing, etc.), and the amount that is refundable to the government program. In *every* example Omnicare itself identified the claims as being "refundable." Exhibit B is a summary sheet of Wave I which reflects the overall findings of the claims level information such as that contained in Exhibit A. Exhibit C reveals specific instances of DMERC region A paying claims for a specific date of service despite there being no evidence of "proof of delivery". Again, Omnicare identified all of these claims as being "refundable." Exhibit D is similar to Exhibit B in that it is a summary sheet for Wave II while Exhibit E identifies claims level Wave II information for Sterling Healthcare --- again with the beneficiaries name redacted. With respect to Count II and "newly acquired pharmacies", Exhibits F and G identify specifically the "order processing" error rates associated with the facilities and a claims review of an individual pharmacy, respectively. Again, Omnicare identified a substantial number of claims where physician orders were missing and delivery tickets absent.

Defendant's assertion that Relator has "failed to provide a basis upon which to extrapolate the data he provided beyond the probe-audit samples" bears special attention. First, this is the pleading stage. As such, the question for the Court to consider is whether the Relator has appropriately pleaded a cause of action. Whether there is one false claim or ten thousand false claims matters not with respect to this question. As a matter of fact, the Government need

[38] For each of the "example" states, the following represents authority from each State Medicaid program requiring that all DME items dispensed have an order/prescription from the treating practitioner on file prior to dispensing the item: Colorado: 10 CCR 2505-10 8.590.4.D.; Illinois – Handbook for Providers of Medical Equipment and Supplies, Chapter M-203; Louisiana – Durable Medical Equipment Provider Manual, Chapter 18 of the Medicaid Services Manual, Section 18.4; Nevada – Medicaid Services Manual – Chapter 1303.2; Washington - Washington Administrative Code 388-552-200; 388-554-500; 388-543-1100; 388-543-1225.

not sustain, and Relator need not prove, damages in order for a defendant to be liable under the False Claims Act.[39] Second, much of Omnicare's argument appears to address the quantum and quality of evidence Relator has brought to bear in support of his Complaint. Again, this is an inappropriate inquiry at this juncture; when ruling on a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(1) or (b)(6), a court must take all of the factual allegations in the complaint as true and make reasonable inferences in favor of the plaintiff.[40]

Returning to the question of "particularity", the Seventh Circuit has recently clarified what is required of a *qui tam* relator's complaint with respect to Federal Rule 9(b). While reiterating that complaints are required to plead "the who, what, when, where, and how: the first paragraph of any newspaper story," the Court explains that where a complaint "alleges the promise, the intent not to keep that promise, and the details of non-conformity," it narrates with particularity the circumstances of fraud. [41]

The *Lusby* complaint alleged that five contracts between Rolls-Royce and the United States required all of the engine's parts to meet particular specifications.[42] It further alleged that

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[39] *United States v. Hughes*, 585 F.2d 284, 286 n.1 (7th Cir. 1978)(false claim was actionable even though the United States had suffered no measurable damages from the claim); *See also U.S. v. Rogan*, 459 F.Supp.2d 692, 720 (N.D. Ill. 2006); *Varljen v. Cleveland Gear Co., Inc.*, 250 F.3d 426, 429 (6th Cir. 2001) ("recovery under the FCA is not dependent upon the Government's sustaining monetary damages"); *United States ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1421 (9th Cir.1991) ("No damages need be shown in order to recover the penalty") (citing *Rex Trailer Co. v. United States*, 350 U.S. 148, 153 n. 5, 76 S.Ct. 219 (1956)). Further, the legislative history of the 1986 Amendments to the False Claims Act demonstrates that Congress understood that damages were not an element of a cause of action under the False Claims Act. Specifically, the Senate stated that the US "is entitled to recover [civil penalties] solely upon proof that false claims were made, without proof of any damages." S. Rep. No. 99-345 at 8.

[40] *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1940, (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007); *Hecker v. Deere & Co.*, 556 F.3d 575, 580 (7th Cir.2009); *Tamayo v. Blagojevich*, 526 F.3d 1074 (7th Cir. 2008); *Long v. Shorebank Dev. Corp.*, 182 F.3d 548, 554 (7th Cir.1999).

[41] U.S. ex rel. Lusby v. Rolls Royce Corp., 570 F.3d 849, *4 (7th Cir. 2009) (*quoting DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990) and *United States ex rel. Garst v. Lockheed-Martin Corp. et al.*, 328 F.3d 374, 376 (7th Cir. 2003)).

[42] *Id.*

the parts did not do so, that Rolls-Royce knew that the parts were non-compliant, and that Rolls-Royce nonetheless certified that the parts met the contracts' specifications.[43] Differentiating between "pleading" and "proving,"[44] the Court concluded that it is "enough to show, in detail, the nature of the charge, so that vague and unsubstantiated accusations of fraud do not lead to costly discovery and public obloquy."[45] The Court observed that Lusby's accusations were not vague because Rolls-Royce "has been told exactly what the fraud entails."[46]

Defendant contends that "an FCA complaint must link the allegations of fraud to claims for payment."[47] *Lusby* confirms, however, that it is not essential "for a relator to produce the invoices (and accompanying representations) at the outset of the suit" because most relators are unlikely to have such documents unless he or she works in the defendant's accounting department.[48] Acknowledging that, while it is "essential to show a false statement," the Court explained that such a showing is often inferential and that a pleading need not "exclude all possibility of honesty in order to give the particulars of fraud."[49] No complaint, according to the Court, needs to "rule out all possible defenses."[50] With respect to Counts 1 and 2, Relator has pleaded with requisite particularity and Defendant's Motion to Dismiss should be denied.

[43] *Id*.
[44] *Id*., *5.
[45] *Id*., *citing United States ex rel. Clausen v. Laboratory Corp. of America*, 290 F.3d 1301, 1310 (11th Cir.2002). Cf. *Ashcroft v. Iqbal*, 129 S.Ct. 1937 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007).
[46] *Id*.
[47] Memo in Support, pg. 13.
[48] *Lusby*, *4.
[49] *Id*., *5.
[50] *Id*.

UNDER THE PRE-FERA FCA, RELATOR HAS STATED A CAUSE OF ACTION FOR COUNTS I AND II.

In the event the Court determines that the FERA-amended FCA is not applicable, Relator has nonetheless stated a cause of action for both Counts I and II pursuant to the pre-FERA §3729(a)(1).[51] Defendant argues that Relator fails to state a cause of action pursuant to the pre-FERA FCA because Relator failed to plead that Defendant presented any factually false claim to the government for payment. In the alternative, Defendant claims that Relator failed to allege that Defendant falsely certified compliance with any statute or regulation as to the existence of the paperwork referenced in Relator's Complaint.

Relator will not burden this Court by repeating points already made above. As supported by Relator's affidavit attached hereto as Exhibit A, one of the primary purposes of Wave II was to determine whether proper documentation *ever* existed for the Wave I claims. An initial observation about the Wave I results was that, based on the age of the claims, the documentation had simply been misplaced over the course of time. Pat Keefe, Executive Vice President and Chief Operating Officer, wanted to show that Wave I documents had actually been originally present and thereafter lost.[52] Thus, following the Wave I audit, Defendant concentrated the Wave II audit on recently-submitted claims. The Wave II results revealed an error rate comparable to Wave I and that the documents associated with Wave I and Wave II, such as physician orders and proof of delivery receipts, had never existed.[53]

Because the documents substantiating a claim for payment never existed, the claims as originally made, with respect to Count I and II, were false claims pursuant to §3729(a)(1).

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[51] 31 U.S.C. §3729(a)(1), pre-FERA, provided for liability for any person who "knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval."
[52] Exhibit A, Affidavit of John Stone, ¶4.
[53] *Id.*

Without proper documentation to substantiate the claim for payment, Defendant's claims could not be made. Though Defendant has suggested that Relator has failed to plead, for instance, "presentment," the facts of this case do not implicate a situation where a party has made, used, or caused to made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government. It is not, in other words, a case which typically involves subcontractors.[54] Under the facts at bar, the pharmacies that made claims for payment to government programs are in privity with the state and federal government. Liability under §3729(a)(1) is straightforward.

COUNT III
THE NEVADA SYNAGIS INVESTIGATION HAD NOTHING TO DO WITH RELATOR'S ALLEGATIONS

Defendant asserts that the August 31, 2006, settlement between the Nevada MFCU and Omnicare precludes Relator from pleading fraud related to its *use* of the drug Synagis. The subject matter of that settlement is set forth in paragraph 2 of that agreement and is reproduced below from Omnicare's Exhibit 3:

> (i) During November 2003 through April 2004, ACP routinely submitted clams for reimbursement from Nevada Medicaid concerning the utilization of Synagis. Adequate records were not maintained and/or clearly verifiable in regard to three individual dosages of the drug. ACP's billing department submitted claims for these dosages as if all supporting documentation was complete and accurate.
> (ii) ACP failed to discover and/or correct the deficiencies and accepted payment for these claims.
> (iii) Allegations of other situations regarding claims submitted for Synagis also existed concerning the time period of November 2003 through April 2004.

Relator's claims have *nothing* to do with the settlement referenced above. While the settlement expressly resolved claims regarding inadequate records and incomplete and inaccurate

[54] FERA § 4 was intended to address *Allison Engine Co., Inc. v U.S. ex rel. Sanders*, 128 S. Ct. 2123 (2008) and *U.S. ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488 (D.C. Cir. 2004) which held that FCA defendants must present their false claim directly to the government or intend the fraud to be paid with government funds. Because the claims in the instant case are "direct" claims, FERA's legislative "fix" has little, if any, relevance.

documentation, Relator's complaint addresses Omnicare's *use* of the drug. One thing has nothing to do with the other. Specifically, Relator alleges that:

> a. Defendant intentionally ordered excess Synagis and failed to discard the excess medication as required by Synagis' FDA approved label (see, by way of example, the claim level Synagis distribution for Arlington Acquisition I, Inc. attached as Exhibit H);
>
> b. Defendant's facilities engaged in the pattern and practice of stockpiling excess Synagis from previous prescriptions and filling new prescriptions with the excess Synagis from previous patients; and,
>
> c. Defendant's facilities engaged in the pattern and practice of billing State Medicaid for each Synagis vial prescribed while many, if not most, of the new patients' prescriptions were being filled with the facility's stockpiled Synagis excess.[55]

Nothing about the settlement raised any issue about Omnicare's use of the drug. How one bills for a drug and what one does with a drug are two entirely different matters. With this, the (iii) phrase "allegations of other situations regarding claims" cannot possibly serve as a public disclosure because nothing about this phrase exposes any critical elements of the fraud in the public domain.[56]

Relator's Complaint alleges that Defendant stockpiled excess Synagis and used that stockpile to fill new prescriptions so as to maximize Medicaid reimbursement. One will search the Omnicare settlement in vain for any manner of reference to that alleged behavior. Defendant's position that the Nevada investigation addresses the conduct alleged in Relator's Complaint is without a factual basis. This point is made all the more clear by the fact that the settlement specifically covers November 2003 through April 2004. The Complaint Exhibit H covers October 2004 through March 2005. Even if there was a public disclosure of the events occurring

[55] Complaint, ¶49a-c.
[56] *Glaser v. Wound Care Consultants*, 570 F.3d 907, 913 (7th Cir. 2009).

between November 2003 through April 2004, that would not inoculate Omnicare from liability for acts taken from April 2004 through March 2005.

Omnicare's Motion with respect to Synagis is meritless and should be denied.

COUNT IV
MEDICAID PRICING

Relator concedes dismissal of Count IV of his Complaint.

COUNT XXIV
RELATOR HAS STATED A VALID CLAIM FOR RETALIATION

In an effort to protect whistleblowers from employment retaliation, Congress amended the FCA in 1986 to provide whistleblower protection against employment retaliation. Specifically, Section 3730(h) provides, in relevant part:

> Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in terms and conditions of employment because of lawful acts done by the employee, contractor, or agent on behalf of the employee, contractor or agent or associated others in furtherance of other efforts to stop 1 or more violations of this subchapter.[57]

In order to establish a valid §3730(h) claim, a Relator must prove: "(1) his actions were taken 'in furtherance of' an FCA enforcement action and were therefore protected by the statute; (2) his employer had knowledge that he was engaged in this protected conduct; and (3) his discharge was motivated, at least in part, by the protected conduct."[58]

As stated in his Complaint, Relator presented a document (Exhibit J to Relator's Complaint) to Defendant's Internal Audit committee reflecting the deficiencies relative to Defendant's newly acquired pharmacies and that such deficiencies resulted in *fraud* upon

[57] 31 U.S.C. §3730(h).
[58] *Fanslow v. Chicago Mfg. Center, Inc.*, 384 F.3d 469, 479 (7th Cir. 2004); *Brandon v. Anesthesia & Pain Mgmt. Assoc., Ltd.*, 277 F.3d 936, 944 (7th Cir.2002).

Medicare and the various State Medicaid programs.[59] As a result of Relator's protected activity, Defendant's CEO took an adverse employment action against Relator by telling him to "begin looking for other employment."

RELATOR ENGAGED IN PROTECTED CONDUCT

With regard to the first required element of proof under §3730(h), the plain language of the FCA defines "protected activity" as "lawful acts done … in furtherance of an action under this section, including investigation for, investigation of, testimony for, or assistance in an action filed or to be filed."[60] Defendant contends that the conduct described in Relator's Complaint should not be considered a "protected activity" because Relator did not allege that he was acting in furtherance of an FCA action or that an FCA action was a distinct possibility at that time. According to Defendant, Relator was simply performing his duties as Vice President – Internal Audit and was not investigating the possibility of false claims or contemplating bringing a lawsuit against Defendant for potential false claims.

Defendant's contentions are without merit. For an action to be considered a "protected activity" under §3730(h), an employee is not required to possess actual knowledge of the FCA at the time of the activity.[61] Instead, Relator must be investigating into matters which are calculated, or reasonably could lead, to a viable FCA action.[62] As noted by the *Fanslow*, if only those employees who were motivated by the FCA were protected under the Act, "only those with sophisticated legal knowledge would be protected...".[63]

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[59] Complaint ¶249.
[60] 31 U.S.C. §3730(h).
[61] *Fanslow*, 384 F.3d at 479; *See also Childree v. UAP/GA CHEM, Inc.*, 92 F.3d 1140, 1145-46 (11th Cir. 1996)(noting that "nothing in the language of §3730 suggests that its protections are limited to those who were motivated by it"); and, *U.S. ex rel. Hopper v. Anton*, 91 F.3d 1261, 1269 (9th Cir. 1996) (noting that "specific awareness of the FCA is not required for the existence of a "protected activity").
[62] *Neal v. Honeywell Inc.*, 33 F.3d 860, 864 (7th Cir.1994).
[63] *Fanslow*, 384 F.3d at 479..

Defendant references *Fanslow* for the proposition that a relator "must show that an FCA action is a 'distinct possibility' at the time of the investigation for [his] actions to be considered 'protected activity.'"[64]. However, the *Fanslow* court explicitly stated that this proposition should *not* be read to necessitate actual knowledge of the FCA.[65] Instead, the court cautioned that the propositions should be read in concert to create a bifurcated objective/subjective standard that considers whether: "(1) the employee in good faith believes, and (2) a reasonable employee in the same or similar circumstances might believe, that the employer is committing fraud on the government."[66]

Relator's conduct clearly constitutes "protected activity" as contemplated by the statute. The purpose of Relator's audit was to verify whether Defendant's newly acquired pharmacies were in compliance with Medicare and various State Medicaid statutory and regulatory requirements. As described in Count II of Relator's Complaint, after conducting the audit, Relator revealed to Defendant that it was in violation of numerous federal and state regulations and that said violations resulted in fraud upon Medicare and the various State Medicaid programs. Thus, Relator, and any reasonable employee in Relator's position, would believe that Defendant was committing fraud on the government in light of the deficiencies identified in Relator's audit.

DEFENDANT'S HAD NOTICE OF RELATOR'S PROTECTED CONDUCT

In the Seventh Circuit, the scope of notice required depends upon whether the employee is normally engaged in identifying and reporting fraudulent activity.[67] Employees charged with discovering fraud in the normal course of their job duties are called "fraud-alert" employees and

[64] Memo in Support, pg. 27, *citing Fanslow*, 384 F.3d at 480
[65] *Fanslow*, 384 F.3d at 479.-80.
[66] *Fanslow*, 384 F.3d at 480 (quoting *Moore v. Cal. Inst. Of Tech. Jet Propulsion Lab.*, 275 F.3d 838, 845 (9th Cir. 2002).
[67] *Id.* at 484.

necessitate a "heightened notice requirement," which require the employee to utilize terms like "illegal," "unlawful" or "fraudulent" when sharing concerns with the employer. *Id.* Non-fraud-alert employees are held to a "less notice standard" and are only required to show that their employer was aware of the employee's fraud investigation. *Id.*

As Defendant's Vice President of Internal Audit, Relator's was not responsible for discovering fraud in the normal course of his employment. As such, Relator is only required to show that Defendant was aware of his protected activity. In light of the fact that Relator relayed his report findings to Defendant's Internal Audit committee, the facts clearly indicate that Defendant was aware of Relator's protected. Furthermore, even if Relator were considered a fraud-alert employee, Relator's statement to Defendant that the audit evidenced Medicare and State Medicaid fraud would satisfy the Seventh Circuit's heightened notice requirement.

DEFENDANT'S ADVERSE EMPLOYMENT ACTION WAS MOTIVATED BY KNOWLEDGE OF RELATOR'S PROTECTED ACTIVITY

As a final requirement under §3730(h), the Relator is required to show that his discharge was motivated, at least in part, by the protected conduct.[68] Once the plaintiff has made this showing, "the burden of proof shifts to the employer to prove affirmatively that the same decision would have been made even if the employee had not engaged in protected activity."[69]

Initially, it is important to note that anti-retaliation protections under §3730(h) are not limited to termination of employment. Instead, Congress intended to protect whistleblowers against *all* adverse employment actions against employees, including anyone "discharged, demoted, threatened, harassed, or in any other manner discriminated against" because of their

[68] *Brandon*, 277 F.3d at 944.
[69] *Fanslow*, 384 F.3d at 485 (*quoting U.S. ex rel. Yesudian v. Howard University*, 153 F.3d 731, 736 n.4 (C.A.D.C. 1998).

involvement in "protected conduct" under the FCA.[70] The Ninth Circuit has equated employer retaliation under the FCA with "adverse employment action under Title VII."[71] As such, the *Moore* court found that a cognizable §3730(h) claim can rest on employer action that "is reasonably likely to deter employees from engaging in activity protected" by the FCA.[72] The Ninth Circuit's broad interpretation of what constitutes an adverse employment actions is consistent with the spirit of §3730(h).

Defendant's sole argument relative to this requirement is that "Relator fails to allege the date when he was constructively discharged."[73] As mentioned above and pled in his Complaint, after Relator presented the audit document to Defendant's Audit committee, Defendant's CEO effectively discharged Relator. Although Relator is not required to plead a specific date on which this event occurred, the precise date of the Audit Committee meeting can be obtained from a review of Defendant's meeting minutes following Thanksgiving, 2008. At that meeting, Mr. Joel Gemunder stated that he was "restructuring internal audit including its people and processes."[74] As Relator recalls, Relator was thereafter approached by Mr. David Froesel Jr. on or about December 1, 2009 and told that he needed to find other employment.

In light of the fact that the only thing which differentiated one day of employment from another was Relator's use of the word "fraud", a reasonable person can conclude that Defendant's adverse employment action was motivated by Relator's protected conduct. It is not a stretch, in fact, to conclude that Relator's protected activity was the *primary* motivating factor in Defendant's adverse action against him.[75] Relator did not simply quit his job. He was told, in

[70] 31 U.S.C. §3730(h).
[71] *Moore v. California Inst. Of Tech. Propulsion Lab.*, 275 F.3d 838, 847-48 (9th Cir. 2002).
[72] *Id*.
[73] Memo in Support, pg. 30.
[74] Exhibit A, Affidavit of John Stone, ¶5.
[75] *Hecker v. Deere & Co.*, 556 F.3d 575, 580 (7th Cir.2009).

no uncertain terms, to find employment elsewhere.[76] Relator has adequately pleaded such facts and he is entitled to have them accepted as true.

WHEREFORE, Relator prays this Court deny Defendant's Motion to Dismiss in its entirety. In the event Defendant's Motion is granted in any respect, Relator prays this Court grant Relator leave to amend his Complaint to correct any identified deficiency.

Respectfully Submitted,

/s/ Dale J. Aschemann

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[76] *Id.*

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

UNITED STATES OF AMERICA, *ex rel.* JOHN STONE, and the States of Illinois, California, Florida, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, Virginia and Wisconsin, ex re. JOHN STONE,	)	
Plaintiffs,	)	Honorable James B. Zagel
v.	)	Civil Action No: 1:09-cv-04319
OMNICARE, INC.,	)	Magistrate Morton Denlow
Defendant.	)	

CERTIFICATE OF SERVICE

I hereby certify that on the 12th day of January 2011, I electronically filed **Relator's Response In Opposition To Omnicare, Inc's Motion To Dismiss Relator's Complaint** with the Clerk of Court using the CM/ECF system which will send notification of such filing(s) to the following:

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IN THE UNITED STATES DISTRICT COURT
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OMNICARE, INC.,	)	Magistrate Morton Denlow
Defendant.	)	

AFFIDAVIT OF JOHN STONE

NOW COMES the Affiant, John Stone ("Relator"), on this 12th day of January 2011, being of legal age and under no disability, and after being first duly sworn upon his oath, states as follows:

1. Paragraph 33 of my Complaint states that "[w]ithout further examination of the claims submitted during the period 2000 through 2005 – despite an enormous error rate and having conducted only a "probe" audit – and with knowledge of the Wave II audit results, Defendant reimbursed each of the respective DMERC Regions A, B, C and D for the Wave I findings and falsely asserted that the Medicare program was made whole by that payment."

2. I reviewed one or more draft letters to the DMERC Regions pertaining to the reimbursement described above and at least one of those draft letters was dated March 2009. A draft letter was to accompany each of the respective reimbursements.

3. It is my recollection that the actual repayment to the DMERC regions did not occur until several months after the letters were drafted.

4. Following the Wave I audit of claims for the years 2000-2005, the Wave II audit was conducted for the purpose of reviewing more recent claims (2008) during the year in which they occurred. This was done because Pat Keefe, then the Executive Vice President and Chief Operating Officer, wanted to show that Wave I documents had actually been originally present and thereafter lost. Wave II, however, revealed an error rate comparable to Wave I and that the documents associated with the Wave I and Wave II claims had never existed.

5. It is my recollection that on December 1, 2009, Mr. David W. Froesel, Jr. informed me that I would need to seek an alternative form of employment. This occurred in follow-up to the November 2008 Audit Committee meeting in which Mr. Joel F. Gemunder stated that he was "restructuring internal audit including its people and processes."

I declare under penalty of perjury that the foregoing is true and correct.

Further Declarant John Stone sayeth not.

/s/ John Stone, with Consent
John Stone